SANI-SPRAY- isopropyl alcohol spray
Freedom Technologies

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Sani-Spray

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

a. Isopropyl Alcohol (75%, v/v) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
b. Glycerol (1.45% v/v).
c. Hydrogen peroxide (0.125% v/v).
d. Sterile distilled water or boiled cold water.

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Isopropyl Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age
- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.
Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

glycerin, hydrogen peroxide, purified water USP

Package Label - Principal Display Panel

Butler CHEMICALS, INC.

SANI-SPRAY

SURFACE & HAND SANITIZER

DESINFECTANTE DE MANOS Y SUPERFICIES

DESCRIPTION:
High quality isopropyl alcohol sanitizer that meets or exceeds the requirements of the FDA. Sanitizes to help reduce bacteria that potentially can cause disease. Helps prevent cross-contamination. Recommended for repeated use.

TECHNICAL SPECS:

pH	5-7
Fragrance	N/A
Color	Colorless Liquid
Specific Gravity	1
Water Solubility	N/A

PACKAGE HANDLING AND STORAGE

Size	Pkg.	Dimensions	Weight
1-Quart	BOTTLE	N/A	N/A

Store this product out of direct sunlight in a cool dry area. For best results, use with in 12 months. Refer to SDS for more specific information.

DISCLAIMER:
This information is based on data considered accurate. However, no warranty is expressed or implied regarding the accuracy of this data or the results obtained from the use thereof. Butler Chemicals, Inc. assumes no responsibility for personal injury or property damage to the Vendee, User, or Third Parties caused by the material. Such Vendees or Users assume all risks associated with the use of this material. The contents of this document are subject to change with out notice.

CONSULT YOUR BUTLER CHEMICAL SALES REPRESENTATIVE FOR PROPER DILUTING AND USE PROCEDURES.

Distributed by:
Butler CHEMICALS, INC.
(714) 630-7625

IN CASE OF TRANSPORTATION OR MEDICAL EMERGENCY CALL:
INFOTRAC
1-352-323-3500 (International)
1-800-535-5053 (North America)

HMIS/NFPA Hazard Rating

HEALTH	1
FLAMMABILITY	0
REACTIVITY	1
PROTECTION	B

3070 E. CEENA CT. • ANAHEIM, CA 92806 • (800) 331-3643

SANI-SPRAY

isopropyl alcohol spray

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:80891-102
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOPROPYL ALCOHOL (UNII: ND2M416302) (ISOPROPYL ALCOHOL - UNII:ND2M416302)	ISOPROPYL ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	1.45 mL in 100 mL
HYDROGEN PEROXIDE (UNII: BBX060AN9V)	0.125 mL in 100 mL
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80891-102-01	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Freedom Technologies (057382260)

Establishment

Name	Address	ID/FEI	Business Operations
Freedom Technologies		057382260	manufacture(80891-102)

Revised: 1/2022 Freedom Technologies